

REMARKS

Claims 14-40 are currently pending in the application. By this amendment, claim 14 is amended to correct a minor grammatical oversight. Claims 35-49 are added for the Examiner's consideration. Claims 35-40 read on the elected species of figures 8-17. The above amendments do not add new matter to the application and are fully supported by the specification. For example, support for the added claims is provided at Figures 8-17 and at pages 13-16 of the specification. Reconsideration of the rejected claims in view of the above amendments and the following remarks is respectfully requested.

Amendments to the Claims

Applicants have amended claims in this application. Applicants are not conceding in this application that those claims are not patentable over the art cited by the Examiner, as the present claim amendments are only for correcting a grammatical error. Applicants respectfully reserve the right to pursue the original claims and other claims in one or more continuations and/or divisional patent applications.

Incomplete Office Action

Applicants note that the Examiner has not provided a complete office action. For example, the Examiner has not addressed any features of claim 24, nor has the Examiner indicated that such claim is in condition for allowance or withdrawn from consideration. Applicants submit that for this reason a clear issue was not developed between the Examiner and Applicants. As such, the next Office Action, which should clarify this issue, *cannot* be made final.

According to MPEP 706,

Before final rejection is in order a clear issue should be developed between the examiner and applicant. To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection.

Additionally, MPEP 706.07(a) notes:

Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). ...

Furthermore, a second or any subsequent action on the merits in any application ... will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17 (p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art.

Accordingly, Applicants respectfully submit that the Examiner may not make the next action final, as in the previous Office Action a "clear issue [was not] developed between the examiner and applicant".

35 U.S.C. §112 Rejection

Claims 14 and 16 were rejected under 35 U.S.C. §112, 2nd paragraph. This rejection is respectfully traversed.

According to MPEP §2173.02, the test for definiteness under 35 U.S.C. §112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

From the pending rejection, the Examiner's rejection appears to be directed, not to the clarity of the claim language, but to the breadth of the claim. As is known, undue breadth of the claims is resolved through application of the prior art under 35 U.S.C. § 102, not through formal rejections under 35 U.S.C. § 112. If the Examiner believes the invention is not properly disclosed, then an appropriate rejection should be made. If the Examiner feels the claims should include further description of a recited feature or elements in the claims, the Examiner should

find suitable prior art to show that Applicants are claiming more than they are entitled to under the patent statutes.

In any event, the Examiner is unclear as the features of claim 14 and, more specifically

what is meant by “a lower part pivotably connected to the upper part via an articulation device in Fig. 8 of species 2.

First, Applicants submit that the elected species is related to FIGS. 8-17. Second, the specification and figures are very clear as to what is the lower part, as well as connecting the lower part to an articulation device.

Referring to FIG. 8, for example, the lower part is shown partially by the guide 23 and FIG. 9 shows the lower part 20, which the guide makes part thereof. The relationship between the guide and the lower part is clearly defined in the specification. Also, the specification defines the upper part at reference numeral 10, which is also shown in FIG. 8. For example, although admitting that FIG. 3 is not part of the elected species, paragraph 0056 of the published application provides guidance with reference to FIG. 8 and more specifically, the lower part 20, the guide 23 and the relationship with the articulation. More specifically, paragraph 0056 discloses:

[0056] FIG. 3 shows the prosthetic knee joint 1 in a partial cross-sectional view illustrating the configuration of the resistance device 30 with a hydraulic piston 30' which is connected to the upper part 10 via a piston rod 31. The piston 30' moves inside a cylinder 26 which is formed by and through the guide 23. The guide 23 is configured as a cylinder wall and forms an integral structural component of the lower part 20. Arranged at the lower end of the cylinder 26 there is a closure device via which the cylinder 26 can be filled with a hydraulic fluid.

As to the articulation device, FIG. 8 clearly shows an articulation device at, for example, reference numeral 12. More specifically, paragraph 0058 of the published application discloses:

[0058] FIG. 8 shows an alternative structure of the articulation device in which the upper part 10 is articulated directly on the bearing bracket 21, and the piston rod 31 is connected to the rear section 13 of the upper part via a rear articulation lever 12.

Accordingly, Applicants respectfully submit that the terminology used in claim 14 is clear and definite, and well defined in the specification such that one of ordinary skill in the art would readily understand that invention as being clear, definite and precise.

As to claim 16, the Examiner indicates that it is unclear from the figures as to how the lower part freely extends on the system, as the lower part is attached to the upper part and cylinder. Applicants direct the Examiner's attention to FIG. 11 which shows this feature. Also, paragraph 0062 of the published application discloses:

[0062] FIG. 11 shows the switched state of the main valve 61, that is to say hydraulic fluid can flow from the lower chamber into the upper chamber through the bores 32, so that a downward movement of the piston 30' is permitted. In this states the valve 61 allows the piston 30' to move freely in both directions, which signifies free mobility of the knee joint.

Accordingly, Applicants respectfully submit that the terminology used in claim 16 is clear and definite, and well defined in the specification such that one of ordinary skill in the art would readily understand that invention as being clear, definite and precise.

In view of the above remarks, Applicants request that the rejection over claims 14 and 16 be withdrawn.

35 U.S.C. §102 Rejection

Claims 14, 16, 17, 22 and 23 were rejected under 35 U.S.C. §102(b) for being anticipated by U.S. Patent No. 5,904,721 issued to Henry. This rejection is respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP §2131. Applicants submit that the applied art does not show each and every feature of the claimed invention.

Independent Claim 14

Claim 14 recites,

A prosthetic knee joint, comprising:
an upper part having a fastening device adapted for a receptacle for a leg stump;
a lower part pivotably connected to the upper part via an articulation device; and
a resistance device having adjustable resistance and configured to act as a lock which, via a mechanical control device and as a function of an angle, blocks a flexion of the articulation device in a flexed position within a definable angle range,
wherein the lower part is freely pivotable in the flexion direction outside the definable angle range without action of the resistance device.

Applicants submit that these features are not taught by Henry.

The Examiner is of the opinion that Henry shows:

Regarding claim 14, as best understood, Henry discloses a prosthetic knee joint, comprising: an upper part 1 (Fig. 1A) having a fastening device 2 (Fig. 1A) adapted for a receptacle for a leg stump; a lower part 8 (Fig. 1A) pivotably connected to the upper part via an articulation device 28 (Fig. 1A); and a resistance device (piston, 22; Fig. 1A) having adjustable resistance (col. 4, lin. 46-55) and configured to act as a lock (the piston's upper and lower limits in the pneumatic cylinder allow for the adjustable resistance of the device; Fig. 1A) which, via a mechanical control device (rod, 21; Fig. 1A) and as a function of an angle, blocks a flexion of the articulation device in a flexed position within a definable angle range (col. 4, lin. 46-55), wherein the lower part 8 (Fig. 1A) is freely pivotable in the flexion direction outside the definable angle range without action of the resistance device (the lower part 8 will continue to be pivotable outside of the maximum flexion angle if the resistance device or piston 22 did not stop the flexion).

Applicants agree that Henry shows an upper part and a lower part, as well as a resistance device. Applicants also submit that it would appear that the prosthetic knee joint can be adjusted by use of air valves; however, Applicants are of the opinion that Henry does not show, for example, (i) an adjustable resistance configured to act as a lock which, (ii) via a mechanical control device and as a function of an angle, (iii) blocks a flexion of the articulation device in a

flexed position within a definable angle range, wherein the lower part is (iv) freely pivotable in the flexion direction outside the definable angle range without action of the resistance device.

More specifically, referring to FIGS. 1A and 1B, Henry shows an upper part of the prosthetic component constituted by a platform 1. The lower part is essentially constituted by a tube 4, which is intended to receive in a socket 5 a tube extended by an ankle and foot (not shown). (See, col. 3, line 65 to col. 4, line 4.) As disclosed at col. 4, lines 5-15:

The platform 1 and the tube 4 are connected to each other by an assembly of front 6, 7 and rear 8, 9 links forming a deformable prism. These, respectively front and rear, connection elements are pivoted about axes 10, 11, 12, 13 supported by bearings 14 and 15, arranged respectively at the front of the platform 1 and the upper part of the tube 4 and by bearings 16 and 17 arranged respectively at the rear of the platform and the upper part of the said tube. The rear links 8, 9 are unitary and form a single yoke. The bearings 14, 15, 16, 17 are ball, rolling element bearings.

As disclosed at col. 4, lines 15-17, the above arrangement permits a movement of the upper part of the prosthesis with respect to its lower part, about a variable axis of rotation.

In Henry, the tube 4 is closed at its lower end by the socket 5 serving as the connection device for the prosthetic elements of the bottom of the leg. The upper part of the tube 4 is closed by a plug 18 incorporating a bearing 19 and a double seal 20 under oil pressure through which passes the upper rod 21 of the piston 22. The piston 22 has a lower rod 23 sliding in a support 24 provided with a bearing 25 and fixed on the socket 5 in a manner to ensure its appropriate guidance in the tube 4. The upper rod 21 is provided with a yoke 26 inside which, around an axis of a bearing 27, is pivoted a link 28 making connection with the upper platform 1, which latter has a yoke 29 equipped with a bearing 30. (See, col. 4, lines 25-45.)

The piston and cylinder arrangement also includes a compression spring 31 which contributes to maintaining the stability of the assembly of the piston 22 and rods 21, 23 in each of these two positions of rest (col. 4, lines 53-55). The upper 40 and lower 41 chambers communicate by an air duct 32, 33 connected to the body of the cylinder by unions 34, 35. A flat elastomeric seal 38 ensures air tightness. The piston 22 also has a peripheral O-ring 39, in order to isolate each of the two chambers 40, 41 from each other. According to Henry, at col. 5, lines 33-36, a non-return valve 43 is in communication with the air ducts 32, 33 to compress ambient

air into the chambers 40, 41 with an external inflation device. It would appear that this mechanism may make the resistance of the prosthetic adjustable. However, these features would not provide any locking mechanism, nor would such feature block a flexion of the articulation device in a flexed position within a definable angle range.

In operation, according to Henry, supposing that the air duct 32, 33 interconnecting the chambers 40 and 41 is closed, if the piston 22 descends into the cylinder 42, the pressure P2 increases and the pressure P1 diminishes. Using a simple calculation, according to Henry, if the piston 22 is displaced by x, the differential pressure P between the two faces of the piston is proportional to P0 x. Importantly, as disclosed at col. 5, lines 23-32,

If $P_0 = P_a$, upto angles of inclination of the order of 30° or 40° of the platform 1 relative to its horizontal rest position, an inclination which causes the piston 22 to descend, P is so low that the return force does not have the required value.

On the other hand, if $P_1 = P_2 = P_0 = 7$ bar, for the same descent of the piston 22, a differential pressure P of the order of 6 bar is created. The return force is then strong and the propulsive force is considerable, even if the angle of inclination is low, of the order of a few degrees.

Also, as discussed at col. 5, lines 47-55,

If the pressure at rest inside the pneumatic system is substantially equal to the atmospheric pressure, the knee has the characteristics of the knee already known in orthopaedics, and if the pressure at rest inside the pneumatic system is above atmospheric pressure, the knee then has characteristics for damping pendular movement tending towards or having the action of the hydraulic knee, as a function of the level of pressure charged into the pneumatic system, this level being able to be set by the patient according to his wishes.

Although these passages show the operation of the prosthetic joint of Henry, they certainly do not describe any locking mechanism or blocking a flexion of the articulation device in a flexed position within a definable angle range. Instead, these passages merely describe that the level of pressure can be set by the user, and that propulsion forces of the device can act as a dampening.

Also, Henry specifically discusses the different modes of operation in connection with FIGS. 4A to 4E, and as summarized by respective Tables 1 to 5. None of these modes of operation explain a locking mechanism or blocking of a flexion, as recited in the claimed invention. Specifically, according to Henry,

In FIG. 4A, referring to flexure, for which the movement of the piston is downwards as shown by the arrow 60, the flow of air being displaced from the lower chamber 41 to the upper chamber 40 is referred to by the arrows.

In FIG. 4B, referring to the extension, for which the movement of the piston is upwards as shown by the arrow 61, the flow of air being displaced from the upper chamber 40 to the lower chamber 41 is that referred to by the arrows.

In FIG. 4C, referring to inflation at the same pressure of the two chambers 40 and 41 forming the pneumatic cylinder 42 with an inflation device 62, which can be manual or otherwise, whilst the knee is at rest, the inflow of charged air is referred to by the arrows.

In FIG. 4D, referring to auto-inflation of the prosthetic component according to the invention, by alternative movements of flexure and extension of the leg, the flow of air is represented according to whether the simultaneous movement of the piston 22 is descent (flexure), in which case the ambient air is aspirated by the valve 44 to the upper chamber 40 and at a lower pressure than that in the lower chamber 41, or rising of the piston (extension), in which case the air present in the upper chamber is returned to the lower chamber, of which the internal pressure increases substantially relative to the initial situation, and so on.

In FIG. 4E there is shown the emptying of the system with the valve 63 when open whilst the knee is in the rest position.

With the above understanding, Applicants submit that there is no device in Henry that would act as a lock. Simply, Henry provides no locking. Instead, the resistance device (piston 22) includes springs and air valves for dampening of the device, but none of these features are designed or configured to act as a locking mechanism, as required by the claimed invention. Also, although the resistance device appears to be adjustable, by the user, it is not designed to block a flexion of the articulation device in a flexed position within a definable angle range.

Simply, Henry has no mechanism that would block flexion, much less allow the lower part to be freely pivotable in the flexion direction outside the definable angle range without action of the resistance device. Instead, it would appear from the configuration of Henry that the resistance device (piston 22) is required for the flexion, for without moving the resistance device (piston 22), there is no motion available.

Lastly, it would appear that the Examiner is of the opinion that the limits of the dampening device (hydraulic piston) are defined by the end stops, especially the flexion is limited by the support 24. The opinion that outside or beyond the definable angle range the lower part is freely pivotable in the flexion direction is disclosed in Henry if the resistance device did not stop the flexion is not possible because after reaching the maximum flexion angle there is no further flexion possible. If flexion would be possible, the maximum flexion angle would have been reached.

Dependent Claims

Claims 16, 17, 22 and 23 are dependent claims, depending from a distinguishable independent claim. By virtue of these dependencies, claims 16, 17, 22 and 23 are also distinguishable.

Features of these claims also stand on their own merits. For example, claim 23 recites that the hydraulic or pneumatic unit has a controllable valve system which is arranged inside a piston guided in a cylinder. The Examiner is of the opinion that this feature is shown in FIGS. 4A and 4B as the controllable valve system 63. This is not accurate. The controllable valve system 63 is not disclosed to be inside a piston guided in a cylinder. In fact, Henry is completely silent as to the location of the valve 63.

Accordingly, Applicants respectfully request that the rejection over claims 14, 16, 17, 22 and 23 be withdrawn.

New Claims

Claims 35-48 are newly added. These claims are directed to the elected species. Claims 35-48 are dependent claims, depending from a distinguishable base claim. By virtue of these dependencies, claims 35-48 are also distinguishable.

Applicants further submit that these claims are distinguishable on their own merits and should be passed to issuance. For example, the applied reference does not show the features of the valves, configuration and switching of the valves, the control rod centrally within a piston which can be used to control the valves, as well as the configuration of the control rod, to name a few of the features recited in these newly added claims.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that all of the claims are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue. The Examiner is invited to contact the undersigned at the telephone number listed below, if needed. Applicant hereby makes a written conditional petition for extension of time, if required. Please charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. 50-2478.

Respectfully submitted,



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